U.S. Environmental Protection Agency Antimicrobials Division May 28, 2013 Page Three



found in Antimicrobial Copper Alloys, and has different physical and chemical properties, including durability. This misidentification of the active ingredient sows confusion in the marketplace as consumers are likely to associate the product erroneously with the demonstrated performance of solid Antimicrobial Copper Alloys.

CDA appreciates and actively supports the efforts of EPA to promote a proper understanding of the role of antimicrobial products in addressing infection-causing bacteria. To do so effectively, the agency must ensure, as it has with Antimicrobial Copper Alloys, that fundamental questions of efficacy, chemistry, and durability are addressed for all solid surfaces that claim to be antibacterial. If you have any questions or would like further information, please contact CDA counsel, Joseph Green at 202.342.8849 or JGreen@KelleyDrye.com.

Respectfully submitted,

Sudien G. Kirete

Andrew G. Kireta Sr. President and CEO

Copper Development Association Inc.

cc: Steve Bradbury (Bradbury.Steven@epa.gov)

Bill Jordan (Jordan. William@epa.gov)

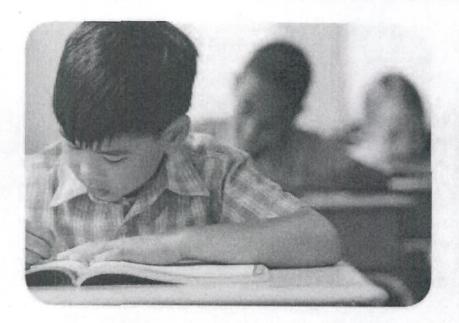
Jeff Kempter (Kempter.Carlton@epa.gov)

Jennifer McLain (Mclain.Jennifer@epa.gov)

Brian Joffe (Joffe.Brian@epa.gov)

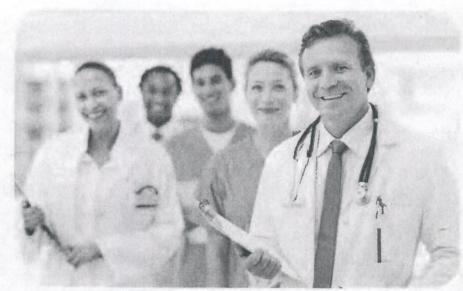
Dennis Edwards Edwards. Dennis@epa.gov)

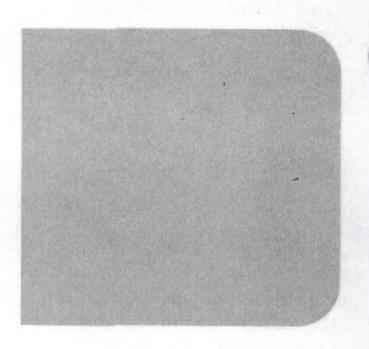
Phil Ross (Ross.Philip@epa.gov)











EOS

PROTECTED SOLID SURFACE



What is Copper?

Copper is required by both plants and animals for survival. It naturally occurs around the world from the United States to Australia. Copper has natural antimicrobial properties that kills a range of bacteria, fungi and viruses.

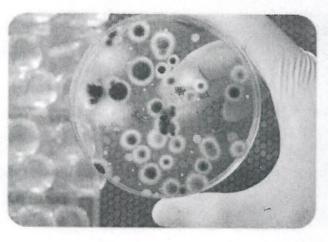
What is EOS?

Cupron Enhanced EOS Solid Surface is a non-porous fully tested blended solid surface material with all the inherent benefits of solid surface such as integral bowls and backsplashes and seamless applications.

What is Cupron?

Cupron, is a platform technology that utilizes the qualities of copper oxide and integrates copper oxide into textiles, latex and other polymeric products during manufacturing. These copper oxide infused polymers transform the material into which they are embedded into a material with built-in antimicrobial product protection against microorganisms such as bacteria and fungi.

Independent testing laboratories have demonstrated Cupron's efficacy in deactivating a wide variety of microorganisms . . . Cupron's proprietary copper oxide compound is natural and long lasting and is biocompatible for non-intrusive medical devices.



Cupron Technology has been proven to kill the following

Bacteria

Pseudomonas aeruginosa Enterococcus faecalis (VRE) Escherichia coli (E. coli) Straphylococcus aureus (MRSA)

Fungus

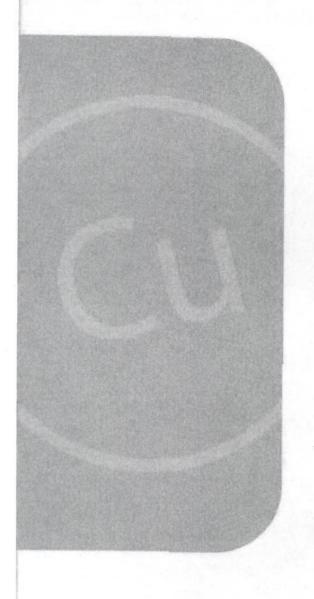
Tricophyton rubrum (foot fungus) Candida albicans Aspergillus niger

Virus

HIV 1

Influenza (H1N1) (Swine flu) Measles



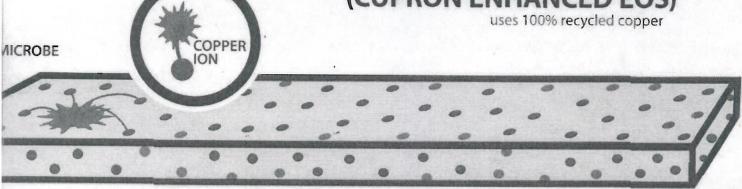


How EOS Solid Surface Cupron Technology Works?

Since Egyptian times, Copper has been known as a microbial killer. While the exact reasons for copper's negative effect on microbes are not fully known, it is generally agreed that copper ions cause a series of damaging effects on bacterial, fungal and viral cells. Some of the common theories are that the copper causes leakage of potassium or glutamate through the cells outer membrane, the copper disturbs the osmotic balance, the copper binds to proteins that do not require copper and copper causes oxidative stress by generating hydrogen peroxide. By combining the extremely hygienic non-porous nature of EOS Solid Surface with the tested cutting edge technology of Cupron, EOS Solid Surface is able to offer hospitals, schools, hospitality and homeowners a defense against the rising tide of the planets' microbes Each sheet of Cupron Enhanced EOS Solid Surface is infused with Cupron technology on all exposed surfaces. Hence, no matter where the sheet is cut, or what part of the sheet is exposed, the Cupron is there to kill the microbes that land on it.

Cupron is not a film or liquid chemical application. In fact, the Cupron particulate within the EOS slabs can actually be seen by the human eye. The mixture of the Cupron particulate into the EOS makes the power and effectiveness of the copper indefinite and it cannot be worn off or become less effective over time.



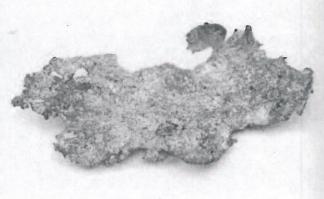


EOS Solid Surface with Cupron

The Safety of Copper

Cupron's active ingredient is Copper. Copper is an essential mineral that we have to ingest on a daily basis in order to survive. Humans metabolize Copper extremely efficiently and the risk of Copper toxicity is exceptionally low, especially due to dermal contact.

Ninety-five percent of the Copper in the world is in the natural form of Copper oxide which is the basis for Cupron's technology. Therefore, the technology is based on natural material. It is non-polluting regarding heavy metals in the water system due to being a non leaching technology.



There are no changes necessary to any production systems and no changes necessary for the consumer in using the product. Cupron's technology has undergone extensive independent laboratory testing and has a long history of safe use. It is registered with the US EPA for use as a fiber preservative and Cupron products can be sold and marketed in the United States by official permission of the US EPA.



Antimicrobial Efficacy

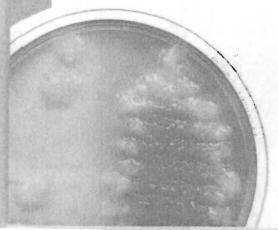
In 2008 the US Environmental Protection Agency registered 275 copper alloys with Public Health claims. The registration means that the EPA recognizes the antimicrobial properties of copper. All Public Health claims must be supported by extensive testing under EPA protocols in an independent laboratory that adheres to OECDC (Organization for Economic Cooperation and Development) Good Laboratory Practice guidelines.

The Rising Cost and Rate of Microbial Infections

80% of infectious diseases are transferred by touch (1). From Medicare's recent ruling that it will not cover "preventable" conditions resulting from hospital stays, including secondary infections, and the incredible cost to the public and private healthcare system of systemic healthcare acquired infections, Cupron Enhanced EOS Solid Surface is not only a powerful potential disease prevention tool, but a sensible economic investment.

 Boone, S. A., & Gerba, C. P. (2007). Significance of fomites in the spread of respiratory and enteric viral disease. Applied and Environmental Microbiology, 73(6), 1687-96. doi: AEM.02051-06.

EOS Surfaces, LLC • 2500 Rodman Avenue, Portsmouth, VA 23707 800-719-EOS1 • P: 757.393.3671 • F: 757.393.3672 • www.eos-surfaces.com





GEO

P; 757-393-3671 F; 757-393-3672 www.eos-surfaces.com

Cupron

Kenneth G. Trinder, II CEO/President

kgt@eos-surfaces.com 2500 Rodman Ave Portsmouth, VA 23707

HCDII--Nashville

EOS Surfaces with CuPron Booth

erense

The power of copper

and natural mineral cov Based on the recycled

. florides ongoing protection

THE BUSINESS WORKENED HT.

as background

Over 99,000 deaths per year in their

waraf microbial Killer

I he numbers

are scary

Broad spectrum effer

ootwear, military tons.

The Cupron Difference

Found in wound descri Environmentally there

HAKINGTH

- \$13,973 average cost per infection • 14 days increased hospital stay 8 days increased ICU stay

\$40,000 increased cost per pater \$4.5 - \$ 5.7 billion in total cost

Upron EOS MAKING THE POWER
OPPER INDEFINITE (U) 2:40) N The Cupron Difference · Based on the recycles and natural mineal con-1101616 **Different** ootwear, military bus ound in wound or Broad spectrum e Environmentally f femides ongoing protection. Jeferise /kiral microbial killer The power of copper mays working in as badgicand ver inferm Sital stay Palcost the following microbes

Bacteria

Pseudomonas aerugine Enterococcus faecalis (1 Escherichia coli (E. coli) Straphylococcus aureus

Fungus

Tricophyton rubrum (for Candida albicans Aspergillus níger

Virus

HIV!

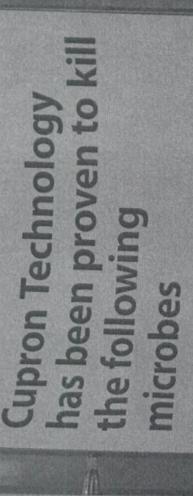
Influenza (HTN1)(Swine Measles



cupron

ENHANCED

Eos Solid Surface with Cupron



Bacteria

Pseudomonas aeruginosa Enterococcus faecalis (VRE) Escherichia coli (E. coli) Straphylococcus aureus (MRSA)

Fungus

Tricophyton rubrum (foot fungus)
Candida albicans
Aspergillus niger

Virus

HIV 1 Influenza (H1N1)(Swine flu) Measles

E OS

Cupron: A New Application of a Proven Technology

cupron

extraordinary products. Every day Cupron focuses on implementing new ways their participated in humanitarian efforts. In October 2010, Cupron's socks were given to the Chilean miners on day 36 of them being trapped in the mines, playing a major Among other places, Cupron has been featured in The Wall Street Journal and has rechnology can help solve some of the world's larger health and lifestyle issues. Cupron, Inc. improves people's lives by transforming ordinary products into tole in protecting the miners' feet and helping enhance their well-being.

In April 2009, the US Environmental Protection Agency registered two forms of Cupron Copper Oxide to make antimicrobial "treated article"

the Chilean miners on day 36 of them being trapped in the mines, playing a majo participated in humanitarian efforts. In October 2010, Cupron's socks were given role in protecting the miners' feet and helping enhance their well-being.

In April 2009, the US Environmental Protection Agency registered two forms of Cupron Copper Oxide to make antimicrobial "treated article" enhanced and wrat mask effective against H1N1 and avian product protection and anti-odor claims for a very large variety of materials and product types. To date, Cupron has 3 registrations with the EPA that permit the use of ensand a European CE Mark for the use of a Cupron tions, Currently these registrations permit anti-odor, Cupron Technology across all non-invasive applicalisting for Cupron Enhanced amti-odor hospital bed Realth' claims language. Cupron also has an FDA Product protection, and anti-dustmite "public

From:

"Green, Joseph J." <JGreen@KelleyDrye.com>

To:

Dennis Edwards/DC/USEPA/US@EPA, Velma Noble/DC/USEPA/US@EPA, Marshall

Swindell/DC/USEPA/US@EPA

Cc:

Karen Leavy/DC/USEPA/US@EPA, Joan Harrigan-Farrelly/DC/USEPA/US@EPA

Date:

05/14/2012 03:25 PM

Subject:

FIFRA Violation - Coating Specialists, LLC

Dear EPA -

On behalf of the Copper Development Association (CDA), please see the information detailed below regarding significant and clear violations of FIFRA by the Coatings Specialists, LLC, which markets a variety of antimicrobial surface coating products (including the SurfaceAide 1000 and SurfaceAide XL product lines). In April 2009, CDA submitted a similar complaint about this company and the antimicrobial claims it makes for its products (see attached letter). We are not aware if any action was taken on this complaint. We urge the agency to act promptly to address these misleading claims.

The SurfaceAide products appear to be registered as "non-public health" products (for use in "treated articles") under (as best we can tell) EPA Registration Number 83135-1. A copy of the presumed registration is attached. However, as made clear by even a quick look at the company website and marketing materials, the products are being successfully marketed as "public health" products that protect the user from disease-causing bacteria and infections (such as in a high-profile deal with the New York Yankees and a number of other professional sports team, the US Army, universities, schools, and other public and private facilities).

Please see below for further details on the misleading claims that appear throughout the Coatings Specialists website. In addition, CDA is deeply concerned about erroneous comparative statements made about copper on the website.

Accordingly, we urge the agency to take strong action to address these misleading marketing activities. Coatings Specialists activities stand in dramatic contrast to the extensive stewardship efforts made by CDA for Antimicrobial Copper Alloys (Reg. No. 82012-1 to -6), which are duly registered public health antimicrobial products.

We would like to meet with the agency to provide any additional information and discuss potential next steps. Please let us know if you think we should address our concerns with other EPA or DOJ officials.

Respectfully Submitted,

Joseph J. Green | Kelley Drye & Warren LLP Washington Harbour, Suite 400 3050 K Street, NW, Washington, DC 20007-5108 202.342.8849 | jgreen@kelleydrye.com www.kelleydrye.com Counsel to the Copper Development Association

From: Adam Estelle [mailto:adam.estelle@copperalliance.us]

Sent: Monday, May 14, 2012 9:54 AM

To: Green, Joseph J. Cc: Harold Michels

Subject: FIFRA Violation - Coating Specialists, LLC

Hi Joe,

We found another coating manufacturer going over the top with claims. I have extracted some of the most clear FIFRA violations from their website below. Most can be found on this page; http://www.antimicrobial.com/services/.

"The Surface Antimicrobial System (SAS) is a comprehensive antimicrobial service developed by Coating Specialists that eliminates the presence of 99.9% of germs and bacteria and delivers continuous antimicrobial protection to surfaces for up to three years. Powered by the durable, high-performance antimicrobial product, SurfaceAide 1000, SAS has been used by some of America's most prominent organizations to kill disease-causing microorganisms like H1N1Flu Virus and MRSA (methicillin-resistant Staphylococcus aureus) and inhibit the growth of microbial contaminants on surfaces ranging from dugouts at Yankee Stadium to training equipment at the U.S. Army's Fort Bliss.

- One application proactively and continually fights the growth of <u>bacteria</u>, mold and fungi on surfaces for 1-3 years, depending on applicator warranty.
- Kills 99.9% of germs and bacteria on surfaces, including disease-causing microorganisms such as: H1N1 Flu Virus, MRSA, Hepatitis, Rhinovirus, Rotovirus, SARS and Mumps.
- Creates an invisible <u>antimicrobial barrier</u> on surfaces that is environmentally friendly, non-toxic and non-sensitizing to human skin.
- Designed to minimize the presence of microbial contaminants in any industry, including: health care, education, sports, hospitality, transportation and veterinary medicine.
- Proactively and continuously prevents odor, staining and deterioration caused by bacteria, mold , mildew and algae."

There is also a lot of technically inaccurate information about copper listed on the site (http://www.antimicrobial.com/technology/):

F . F. 19. 6 Sept.	Coating Specialists Non-Leaching Products	Leaching Antimicrobials Using Silver or Copper
Time	Needs less time to work. It takes less time to destroy a microbe my tearing it apart and puncturing it than it does to slowly poison it.	Needs more time to work. Silver or copper take a
Microbial Adaptation	Microbes can't adapt, or create "super bugs" like MRSA, to the antimicrobial force field created on surfaces and fabrics by SurfaceAide XL, FabricAide and TurfD.	Over time microbes can adapt to poisons like silver or copper, creating "super bugs" like MRSA.
**************************************	Creates an antimicrobial barrier	Must dissipate off the

Efficacy

that does not need to come off surface or fabric each time the surface or fabric to destroy it poisons a microbe, Antimicrobial cell wall, meaning antimicrobial coating is as strong for the millionth microbe it encounters as it was encounters. for the first.

leaving behind less antimicrobial effectiveness for future microbial

Friendly

Yes. SurfaceAide XL. FabricAide and TurfD create a based antimicrobial Environmentally non-toxic, environmentally friendly antimicrobial barrier metals into the

off the surface.

No. Silver and copper products leach heavy on surfaces that does not come environment.

Can you please submit this to EPA on our behalf? Our members greatly appreciate our efforts to maintain the integrity of the registration for copper alloys.

Thanks,

-Adam

Adam A. Estelle

Project Engineer

Copper Development Association Inc.

260 Madison Avenue

New York, NY 10016

Office: 212.251.7232

E-mail Address: adam.estelle@copperalliance.us

http://www.antimicrobialcopper.com

http://www.copper.org

This e-mail and any attachments may contain Copper Development Association Inc ("CDA") proprietary, confidential. privileged, copyrighted, and/or otherwise protected information and are intended solely for the use of the individual or entity addressee(s). If you are not the intended recipient, you are hereby notified that any dissemination, distribution, copying, or action taken in relation to the contents is strictly prohibited and may be unlawful. If you have received this e-mail in error, please notify the sender immediately by replying to this message and permanently delete the original and any copy and printout thereof CDA expressly disclaims any responsibility or liability of any kind in connection with this information or its use by any person or entity and makes no representations or warranties of any kind related to its use, accuracy, completeness, utility, or appropriateness to particular circumstances.

Pursuant to Treasury Regulations, any U.S. federal tax advice contained in this communication, unless otherwise stated, is not intended and cannot be used for the purpose of avoiding tax-related penalties.

The information contained in this E-mail message is privileged, confidential, and may be protected from disclosure; please be aware that any other use, printing, copying, disclosure or dissemination of this communication may be subject to legal restriction or sanction. If you think that you have received this E-mail message in

The revised version you sent this morning looks fine to me. Thanks!

Philip J. Ross United States Environmental Protection Agency Office of General Counsel Pesticides and Toxic Substances Law Office 202-564-5637

Carlton Kempter

OECA, OGC & Bill have concurred on the attach...

10/31/2012 08:12:50 AM

William Jordan

I am OK with the letter as edited by Phil. Thank...

10/27/2012 12:32:52 PM

---- Forwarded by Brian Joffe/DC/USEPA/US on 01/14/2015 12:26 PM -----

From:

Carlton Kempter/DC/USEPA/US

To:

jgreen@kelleydrye.com, harold.michels@copperalliance.us,

Cc:

Jim Jones/DC/USEPA/US@EPA, Steven Bradbury/DC/USEPA/US@EPA, William

Jordan/DC/USEPA/US@EPA, Jennifer Mclain/DC/USEPA/US@EPA, Joan Harrigan-Farrelly/DC/USEPA/US@EPA, Brian Joffe/DC/USEPA/US@EPA

Date:

11/01/2012 06:53 AM

Subject:

EPA Response to Copper Development Association's 9/17/12 letter

Mr. Green--I am pleased to forward EPA's response to the CDA's letter of September 17, 2012, following our meeting of October 23, 2012. As indicated in the letter, kindly contact Ms. Joan Harrigan-Farrelly for further communications or questions for now.

Jeff Kempter Senior Advisor Antimicrobials Division (7510P) Office of Pesticide Programs **Environmental Protection Agency** One Potomac Yard (South Building) 2777 S. Crystal Drive Arlington, VA 22202 703-305-5448 (work)



Copper Development Association.011.Response to CDA Letter of 9-17-12.10-31-12.final.pdf ---- Forwarded by Brian Joffe/DC/USEPA/US on 01/14/2015 12:26 PM ---

From:

"Green, Joseph J." <JGreen@KelleyDrye.com>

To:

Carlton Kempter/DC/USEPA/US@EPA, "harold.michels@copperalliance.us"

<harold.michels@copperalliance.us>.

Cc:

Jim Jones/DC/USEPA/US@EPA, Steven Bradbury/DC/USEPA/US@EPA, William

Jordan/DC/USEPA/US@EPA, Jennifer Mclain/DC/USEPA/US@EPA, Joan Harrigan-Farrelly/DC/USEPA/US@EPA, Brian Joffe/DC/USEPA/US@EPA

11/01/2012 09:23 AM

Date: Subject:

RE: EPA Response to Copper Development Association's 9/17/12 letter

Jeff and EPA team - Thanks for the response and for meeting with us last week. We will be sending a letter detailing our concerns with the competitor's product in the next couple of days.

Hope everyone weathered the "super storm" OK, and enjoyed a happy Halloween.

Joseph J. Green | Kelley Drye & Warren LLP Washington Harbour, Suite 400 3050 K Street, NW, Washington, DC 20007-5108 202.342.8849 | jgreen@kelleydrye.com www.kelleydrye.com
Counsel to the Copper Development Association

From: Kempter.Carlton@epamail.epa.gov [mailto:Kempter.Carlton@epamail.epa.gov]

Sent: Thursday, November 01, 2012 8:53 AM

To: Green, Joseph J.; harold.michels@copperalliance.us

Cc: Jones.Jim@epamail.epa.gov; Bradbury.Steven@epamail.epa.gov; Jordan.William@epamail.epa.gov; Mclain.Jennifer@epamail.epa.gov; Harrigan-Farrelly.Joan@epamail.epa.gov; Joffe.Brian@epamail.epa.gov Subject: EPA Response to Copper Development Association's 9/17/12 letter

Mr. Green--I am pleased to forward EPA's response to the CDA's letter of September 17, 2012, following our meeting of October 23, 2012. As indicated in the letter, kindly contact Ms. Joan Harrigan-Farrelly for further communications or questions for now.

Jeff Kempter
Senior Advisor
Antimicrobials Division (7510P)
Office of Pesticide Programs
Environmental Protection Agency
One Potomac Yard (South Building)
2777 S. Crystal Drive
Arlington, VA 22202
703-305-5448 (work)

(See attached file: Copper Development Association.011.Response to CDA Letter of 9-17-12.10-31-12.final.pdf)

Pursuant to Treasury Regulations, any U.S. federal tax advice contained in this communication, unless otherwise stated, is not intended and cannot be used for the purpose of avoiding tax-related penalties.

The information contained in this E-mail message is privileged, confidential, and may be protected from disclosure; please be aware that any other use, printing, copying, disclosure or dissemination of this communication may be subject to legal restriction or sanction. If you think that you have received this E-mail message in error, please reply to the sender.

This E-mail message and any attachments have been scanned for viruses and are believed to be free of any virus or other defect that might affect any computer system into which it is received and opened. However, it is the responsibility of the recipient to ensure that it is virus free and no responsibility is accepted by Kelley Drye & Warren LLP for any loss or damage arising in any way from its use.

--- Forwarded by Brian Joffe/DC/USEPA/US on 01/14/2015 12:26 PM ----

From:

"Green, Joseph J." <JGreen@KelleyDrye.com>

To:

Joan Harrigan-Farrelly/DC/USEPA/US@EPA,

Cc:

Jim Jones/DC/USEPA/US@EPA, Steven Bradbury/DC/USEPA/US@EPA, William

Jordan/DC/USEPA/US@EPA, Jennifer Mclain/DC/USEPA/US@EPA, Joan Harrigan-Farrelly/DC/USEPA/US@EPA, Brlan Joffe/DC/USEPA/US@EPA, Dennis

Edwards/DC/USEPA/US@EPA, "herold.michels@copperalliance.us"

<haroid.michels@copperalliance.us>, Carlton Kempter/DC/USEPA/US@EPA,

"ross.phil@epa.gov" <ross.phil@epa.gov>

Date:

11/02/2012 10:46 AM

Subject:

Copper Development Association Request to Reconsider Registration of Antimicrobial Cupron

Enhanced EOS Surface

Dear Director Harrigan-Farrelly:

As a follow up to our October 23 meeting, attached please find a letter by which the Copper Development Association (CDA) requests the agency to reconsider the registration of Antimicrobial Cupron Enhanced EOS Surface(EPA Reg. No. 84542-7). Please let us know if you have any questions or would like additional information.

Thank you again for the meeting, which we found productive in airing our concerns about the proliferation of "treated articles" that are being marketed with unregistered public health claims. As we discussed, the Cupron/EOS product was one such "treated article" that was making wide-ranging public health claims for well over a year before obtaining the recent registration. For many reasons, detailed in the attached letter, we believe that numerous vital issues, particularly with regard to efficacy, were not addressed before the registration was issued. In addition, CDA is deeply concerned about the impact of the Cupron/EOS product on the extensive stewardship activities CDA has conducted, at EPA's behest, over the last several years - as well as the questionable track record of Cupron with respect to stewardship of its own products.

We look forward to further discussions with you and the agency.

Please do not hesitate to contact me if you need anything else.

Respectfully submitted,

Joseph J. Green

Counsel to the Copper Development Association

Joseph J. Green | Kelley Drye & Warren LLP Washington Harbour, Suite 400 3050 K Street, NW, Washington, DC 20007-5108 202.342.8849 | jgreen@kelleydrye.com www.kelleydrye.com

Pursuant to Treasury Regulations, any U.S. federal tax advice contained in this communication, unless otherwise stated, is not intended and cannot be used for the purpose of avoiding tax-related penalties.

The information contained in this E-mail message is privileged, confidential, and may be protected from disclosure; please be aware that any other use, printing, copying, disclosure or dissemination of this communication may be subject to legal restriction or sanction. If you think that you have received this E-mail message in error, please reply to the sender.

This E-mail message and any attachments have been scanned for viruses and are believed to be free of any virus or other defect that might affect any computer system into which it is received and opened. However, it is the responsibility of the recipient to ensure that it is virus free and no responsibility is accepted by Kelley Drye & Warren LLP for any loss or damage arising in any way from its use.



CDA Request to Reconsider Registration of Antimicrobial Cupron Enhanced EOS Surface.pdf ---- Forwarded by Brian Joffe/DC/USEPA/US on 01/14/2015 12:26 PM -

From:

Joan Harrigan-Farrelly/DC/USEPA/US

To:

Cc:

"Green, Joseph J." <JGreen@KelleyDrye.com>, Brian Joffe/DC/USEPA/US@EPA, Carlton Kempter/DC/USEPA/US@EPA, Dennis Edwards/DC/USEPA/US@EPA, "harold.michels@copperalliance.us"

<harold.michels@copperalliance.us>, Jennifer Mclain/DC/USEPA/US@EPA.

'ross.phil<'ross.phil@epa.gov'" <ross.phil@epa.gov>, William Jordan/DC/USEPA/US@EPA,>

Date: Subject: 11/05/2012 06:52 AM

Re: Copper Development Association Request to Reconsider Registration of Antimicrobial Cupron

Enhanced EOS Surface

Dear Attorney Green:

This is to acknowledge receipt of your email and the information provided. We will review the information and respond as appropriate.

Thanks

Joan Harrigan Farrelly US Environmental Protection Agency Director, Antimicrobials Division Office of Pesticide Programs 1200 Pennsylvania Ave. N.W. Mailcode 7510P Washington, DC 20460

Physical Address One Potomac Yard 2777 Crystal Dr. Arlington, VA 22202 Phone: 703-603-8914

"Green, Joseph J."

Dear Director Harrigan-Farrelly: As a follow up t... 11/02/2012 12:46:13 PM

---- Forwarded by Brian Joffe/DC/USEPA/US on 01/14/2015 12:26 PM ----

From: To:

"Green, Joseph J." <JGreen@KelleyDrye.com> Joan Harrigan-Farrelly/DC/USEPA/US@EPA,

Cc:

Jim Jones/DC/USEPA/US@EPA, Steven Bradbury/DC/USEPA/US@EPA, William

Jordan/DC/USEPA/US@EPA, Jennifer Mclain/DC/USEPA/US@EPA, Joan Harrigan-Farrelly/DC/USEPA/US@EPA, Brian Joffe/DC/USEPA/US@EPA, Dennis

Edwards/DC/USEPA/US@EPA, "harold.michels@copperalliance.us" <harold.michels@copperalliance.us>, Carlton Kempter/DC/USEPA/US@EPA,

"ross.phil@epa.gov" <ross.phil@epa.gov>

Date:

11/12/2012 10:48 AM

Subject:

RE: Copper Development Association Request to Reconsider Registration of Antimicrobial Cupron

Enhanced EOS Surface

Dear Director Harrigan-Farrelly:

As a follow up to our request to reconsider the registration of the Antimicrobial Cupron Enhanced EOS Surface (84542-7), we are sending a picture (attached and below) taken of the EOS Surfaces booth at the Healthcare Design Show in Chicago, November 4-6, 2012.

As you can see, the company violates several basic tenets of FIFRA and their EPA registration by claiming:

- 1. "keeping us safer" and "protective surface" implying broad protection of human health from infection
- 2. "always cleaning" a statement that, by implying that cleaning is not necessary, contradicts the critical message required by the registration that the surfaces must continue to be cleaned routinely.
- 3. "killing bacteria" does not qualify the broad-spectrum reference to "bacteria" and specify the tested organisms

These violations are consistent with Copper Development Association concerns about the registration of this product and the adverse implications for proper product stewardship.

We appreciate your attention to this matter.

Please let me know if you have any questions or would like further information.

Regards, Joe

Joseph J. Green | Kelley Drye & Warren LLP Washington Harbour, Suite 400 3050 K Street, NW, Washington, DC 20007-5108 202.342.8849 | jgreen@kelleydrye.com www.kelleydrye.com
Counsel to the Copper Development Association

From: Green, Joseph J.

Sent: Friday, November 02, 2012 12:44 PM To: 'Harrigan-Farrelly.Joan@epamail.epa.gov'

Cc: 'Jones.Jim@epamail.epa.gov'; 'Bradbury.Steven@epamail.epa.gov'; 'Jordan.William@epamail.epa.gov'; 'Mclain.Jennifer@epamail.epa.gov';

'Harrigan-Farrelly.Joan@epamail.epa.gov'; 'Joffe.Brian@epamail.epa.gov'; 'Dennis Edwards

(Edwards.Dennis@epamail.epa.gov); 'harold.michels@copperalliance.us';

'Kempter.Carlton@epamail.epa.gov'; 'ross.phil@epa.gov'

Subject: Copper Development Association Request to Reconsider Registration of Antimicrobial Cupron Enhanced EOS Surface

Dear Director Harrigan-Farrelly:

As a follow up to our October 23rd meeting, attached please find a letter by which the Copper Development Association (CDA) requests the agency to reconsider the registration of Antimicrobial Cupron Enhanced EOS Surface(EPA Reg. No. 84542-7). Please let us know if you have any questions or would like additional information.

Thank you again for the meeting, which we found productive in airing our concerns about the proliferation of "treated articles" that are being marketed with unregistered public health claims. As we discussed, the Cupron/EOS product was one such "treated article" that was making wide-ranging public health claims for well over a year before obtaining the recent registration. For many reasons, detailed in the attached letter, we believe that numerous vital issues, particularly with regard to efficacy, were not addressed before the registration was issued. In addition, CDA is deeply concerned about the impact of the Cupron/EOS product on the extensive stewardship activities CDA has conducted, at EPA's behest, over the last several years – as well as the questionable track record of Cupron with respect to stewardship of its own products.

We look forward to further discussions with you and the agency.

Please do not hesitate to contact me if you need anything else.

Respectfully submitted.

Joseph J. Green Counsel to the Copper Development Association

Joseph J. Green | Kelley Drye & Warren LLP Washington Harbour, Suite 400 3050 K Street, NW, Washington, DC 20007-5108 202.342.8849 | igreen@kelleydrye.com www.kelleydrye.com

******************* ATTACHMENT NOT DELIVERED *******

This Email message contained an attachment named image001.jpg which may be a computer program. This attached computer program contain a computer virus which could cause harm to EPA's computers, network, and data. The attachment has been deleted.

This was done to limit the distribution of computer viruses introduced into the EPA network. EPA is deleting all computer program attachments sent from the Internet into the agency via Email.

If the message sender is known and the attachment was legitimate, should contact the sender and request that they rename the file extension and resend the Email with the renamed attachment.

receiving the revised Email, containing the renamed attachment, you can

rename the file extension to its correct name.

For further information, please contact the EPA Call Center at (866) 411-4EPA (4372). The TDD number is (866) 489-4900.

********************** ATTACHMENT NOT DELIVERED *******

Pursuant to Treasury Regulations, any U.S. federal tax advice contained in this communication, unless otherwise stated, is not intended and cannot be used for the purpose of avoiding tax-related penalties.

The information contained in this E-mail message is privileged, confidential, and may be protected from disclosure; please be aware that any other use, printing, copying, disclosure or dissemination of this communication may be subject to legal restriction or sanction. If you think that you have received this E-mail message in error, please reply to the sender.

This E-mail message and any attachments have been scanned for viruses and are believed to be free of any virus or other defect that might affect any computer system into which it is received and opened. However, it is the responsibility of the recipient to ensure that it is virus free and no responsibility is accepted by Kelley Drye & Warren LLP for any loss or damage arising in any way from its use.



CDA Request to Reconsider Registration of Antimicrobial Cupron Enhancedpdf



EOS booth at HCD 11_6_12.jpg.jpg ---- Forwarded by Brian Joffe/DC/USEPA/US on 01/14/2015 12:26 PM -----

From:

Joan Harrigan-Farrelly/DC/USEPA/US

To:

Cc:

"Green, Joseph J." <JGreen@KelleyDrye.com>.

Brian Joffe/DC/USEPA/US@EPA, Carlton Kempter/DC/USEPA/US@EPA, Dennis

Edwards/DC/USEPA/US@EPA, "harold.michels@copperalliance.us" <harold.michels@copperalliance.us>, Jennifer Mclain/DC/USEPA/US@EPA, Jim

Jones/DC/USEPA/US@EPA, "ross.phil@epa.gov" <ross.phil@epa.gov>, Steven Bradbury/DC/USEPA/US@EPA, William Jordan/DC/USEPA/US@EPA

Date:

11/13/2012 09:51 AM

Subject:

RE: Copper Development Association Request to Reconsider Registration of Antimicrobial Cupron

Enhanced EOS Surface

Dear Mr. Green:

Thank you for the message. We will review and follow-up.

Joan

Joan Harrigan Farrelly US Environmental Protection Agency Director, Antimicrobials Division

Office of Pesticide Programs 1200 Pennsylvania Ave. N.W. Mailcode 7510P Washington, DC 20460

Physical Address One Potomac Yard 2777 Crystal Dr. Arlington, VA 22202 Phone: 703-603-8914

"Green, Joseph J."

Dear Director Harrigan-Farrelly: As a follow up t...

--- Forwarded by Brian Joffe/DC/USEPA/US on 01/14/2015 12:26 PM ----

From:

"Green, Joseph J." <JGreen@KelleyDrye.com> Joan Harrigan-Farrelly/DC/USEPA/US@EPA,

To: Cc:

Brian Joffe/DC/USEPA/US@EPA, Carlton Kempter/DC/USEPA/US@EPA, Dennis

Edwards/DC/USEPA/US@EPA, "'harold.michels@copperalliance.us'"

<harold.michels@copperalliance.us>, Jennifer Mclain/DC/USEPA/US@EPA, Jim Jones/DC/USEPA/US@EPA, "ross.phil@epa.gov" <ross.phil@epa.gov>, Steven Bradbury/DC/USEPA/US@EPA, William Jordan/DC/USEPA/US@EPA

Date:

11/13/2012 09:57 AM

Subject:

RE: Copper Development Association Request to Reconsider Registration of Antimicrobial Cupron

Enhanced EOS Surface

Thanks Joan.

Wanted to clarify that the picture was from the Healthcare Design Show in Phoenix (not Chicago), November 4-6, 2012. A similar booth was at the show in Chicago in October. Sorry for the confusion.

Regards, Joe

Joseph J. Green | Kelley Drye & Warren LLP Washington Harbour, Suite 400 3050 K Street, NW, Washington, DC 20007-5108 202.342.8849 | jgreen@kelleydrye.com www.kelleydrve.com

From: Harrigan-Farrelly.Joan@epamail.epa.gov [mailto:Harrigan-Farrelly.Joan@epamail.epa.gov]

Sent: Tuesday, November 13, 2012 11:52 AM

To: Green, Joseph J.

Cc: Joffe.Brian@epamail.epa.gov; Kempter.Carlton@epamail.epa.gov; Edwards.Dennis@epamail.epa.gov; 'harold.michels@copperalliance.us'; Mclain.Jennifer@epamail.epa.gov; Jones.Jim@epamail.epa.gov;

'ross.phil@epa.gov'; Bradbury.Steven@epamail.epa.gov; Jordan.William@epamail.epa.gov

Subject: RE: Copper Development Association Request to Reconsider Registration of Antimicrobial

Cupron Enhanced EOS Surface

Dear Mr. Green:

Thank you for the message. We will review and follow-up.

Joan

Joan Harrigan Farreliy
US Environmental Protection Agency
Director, Antimicrobials Division
Office of Pesticide Programs
1200 Pennsylvania Ave. N.W. Mailcode 7510P
Washington, DC 20460

Physical Address One Potomac Yard 2777 Crystal Dr. Arlington, VA 22202 Phone: 703-603-8914

"Green, Joseph J." ---11/12/2012 12:48:38 PM---Dear Director Harrigan-Farrelly: As a follow up to our request to reconsider the registration of the

From: "Green, Joseph J." < <u>JGreen@KelleyDrye.com</u>>
To: Joan Harrigan-Farrelly/DC/USEPA/US@EPA

Cc: Jim Jones/DC/USEPA/US@EPA, Steven Bradbury/DC/USEPA/US@EPA, William Jordan/DC/USEPA/US@EPA, Jennifer Mclain/DC/USEPA/US@EPA, Joan Harrigan-Farrelly/DC/USEPA/US@EPA, Brian Joffe/DC/USEPA/US@EPA, Dennis Edwards/DC/USEPA/US@EPA, "harold.michels@copperalliance.us" <a href="https://doi.org/10.1016/j.com/nichels@copperalliance.us"/harold.michels@copperalliance.us"/harold.michels@copperalliance.us, Carlton Date: 11/12/2012 12:48 PM

Subject: RE: Copper Development Association Request to Reconsider Registration of Antimicrobial Cupron Enhanced EOS Surface

Dear Director Harrigan-Farrelly:

As a follow up to our request to reconsider the registration of the Antimicrobial Cupron Enhanced EOS Surface (84542-7), we are sending a picture (attached and below) taken of the EOS Surfaces booth at the Healthcare Design Show in Chicago, November 4-6, 2012.

As you can see, the company violates several basic tenets of FIFRA and their EPA registration by claiming:

- 1. "keeping us safer" and "protective surface" implying broad protection of human health from infection
- 2. "always cleaning" a statement that, by implying that cleaning is not necessary, contradicts the critical message required by the registration that the surfaces must continue to be cleaned routinely,
- 3. "killing bacteria" does not qualify the broad-spectrum reference to "bacteria" and specify the tested organisms

These violations are consistent with Copper Development Association concerns about the registration of this product and the adverse implications for proper product stewardship.

We appreciate your attention to this matter.

Please let me know if you have any questions or would like further information.

Regards,

Joe

Joseph J. Green | Kelley Drye & Warren LLP Washington Harbour, Suite 400 3050 K Street, NW, Washington, DC 20007-5108 202.342.8849 | jgreen@kelleydrye.com www.kelleydrye.com
Counsel to the Copper Development Association

From: Green, Joseph J.

Sent: Friday, November 02, 2012 12:44 PM
To: 'Harrigan-Farrelly.Joan@epamail.epa.gov'

Cc: 'Jones.Jim@epamail.epa.gov'; 'Bradbury.Steven@epamail.epa.gov'; 'Jordan.William@epamail.epa.gov'; 'Mclain.Jennifer@epamail.epa.gov';

'Harrigan-Farrelly.Joan@epamail.epa.gov'; 'Joffe.Brian@epamail.epa.gov'; 'Dennis Edwards (

Edwards.Dennis@epamail.epa.gov)'; 'harold.michels@copperalliance.us';

'Kempter.Carlton@epamail.epa.gov'; 'ross.phil@epa.gov'

Subject: Copper Development Association Request to Reconsider Registration of Antimicrobial Cupron

Enhanced EOS Surface

Dear Director Harrigan-Farrelly:

As a follow up to our October 23rd meeting, attached please find a letter by which the Copper Development Association (CDA) requests the agency to reconsider the registration of Antimicrobial Cupron Enhanced EOS Surface(EPA Reg. No. 84542-7). Please let us know if you have any questions or would like additional information.

Thank you again for the meeting, which we found productive in airing our concerns about the proliferation of "treated articles" that are being marketed with unregistered public health claims. As we discussed, the Cupron/EOS product was one such "treated article" that was making wide-ranging public health claims for well over a year before obtaining the recent registration. For many reasons, detailed in the attached letter, we believe that numerous vital issues, particularly with regard to efficacy, were not addressed before the registration was issued. In addition, CDA is deeply concerned about the impact of the Cupron/EOS product on the extensive stewardship activities CDA has conducted, at EPA's behest, over the last several years — as well as the questionable track record of Cupron with respect to stewardship of its own products.

We look forward to further discussions with you and the agency.

Please do not hesitate to contact me if you need anything else.

Respectfully submitted,

Joseph J. Green
Counsel to the Copper Development Association

Joseph J. Green | Kelley Drye & Warren LLP Washington Harbour, Suite 400 3050 K Street, NW, Washington, DC 20007-5108 202.342.8849 | jgreen@kelleydrye.com www.kelleydrye.com

***************** ATTACHMENT NOT DELIVERED

This Email message contained an attachment named image001.jpg which may be a computer program. This attached computer program could contain a computer virus which could cause harm to EPA's computers, network, and data. The attachment has been deleted.

This was done to limit the distribution of computer viruses introduced into the EPA network. EPA is deleting all computer program attachments sent from the Internet into the agency via Email.

If the message sender is known and the attachment was legitimate, you

should contact the sender and request that they rename the file name

extension and resend the Email with the renamed attachment. After receiving the revised Email, containing the renamed attachment, you can

rename the file extension to its correct name.

For further information, please contact the EPA Call Center at (866) 411-4EPA (4372). The TDD number is (866) 489-4900.

******************** ATTACHMENT NOT DELIVERED



May 28, 2013

Susan Lewis, Director
Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Mail Code: 7510P
Washington, D.C. 20460

Re: Submission of Data Demonstrating Inadequate Efficacy of "Antimicrobial Cupron Enhanced EOS Surface" (EPA Reg. No. 84542-7)

Dear Director Lewis:

As a follow up to our November 2, 2012, Request to Reconsider the registration of "Antimicrobial Cupron Enhanced EOS Surface" ("Cupron/EOS Surface") (attached), the Copper Development Association ("CDA") is submitting data showing that the product does not achieve the efficacy testing requirements of the EPA-approved protocols. We understand based on discussions with Deputy Director Jennifer McLain that the agency is preparing a response to CDA's request for reconsideration of the Cupron/EOS Surface registration, and hope that the enclosed test results help inform that response.

The enclosed test data support CDA's concerns (detailed in our November 2, 2012 letter) regarding the antibacterial performance of the Cupron/EOS product, and raise fundamental questions about the viability of the registration. As we have noted previously, these issues must be addressed before the agency should allow the continued marketing and sale of this "public health" product intended to fight infection-causing bacteria in the healthcare environment and other settings.

The data show that, remarkably, the Cupron/EOS Surface failed the basic two hour test for 7 of 10 samples, demonstrating less than the required 99.9% bacterial kill rate. One batch of five samples achieved an average of 99.7% bacteria reductions, and the second batch of five samples only averaged a 96.7% kill rate over the two hour test period. The results of the ten



samples tested are summarized in the chart below.¹ To pass the test, the material must demonstrate greater than 99.9% kill within two hours.

Color	Carrier	Survivors/Carrier	Percent Reduction
	1	1.0 x 10 ³	> 99.9
Beige	2	2.7 x 10 ⁵	93.2
	3	8.6 x 10 ⁴	97.8
	4	2.4 x 10 ³	> 99.9
	5	2.16 x 10 ³	> 99.9
of and Assets	arrant that becounty	An analysis has a box a reserved.	
	1	8.8 x 10 ⁴	97.8
	2	8.4 x 10 ⁴	98.0
Grey	3	1.5 x 10 ⁵	96.2
	4	1.4 x 10 ⁵	96.5
	5	1.8 x 10 ⁵	95.5

Given these results, we urge EPA to reconsider the registration of the Cupron/EOS Surface product. As detailed in our prior letter, it would be arbitrary and capricious to allow such a product to remain registered despite the significant unanswered questions about its long-term durability and antibacterial performance. These test data underscore the substantial concerns and uncertainties that remain about this product.

In addition, CDA calls to the agency's attention the fact that the Cupron/EOS Surface is improperly labeled by identifying the active ingredient as "copper" when, in fact, the active ingredient is cuprous oxide. Cuprous oxide is a distinct chemical from solid copper as

The two 5-sample lots were coded "beige" and "grey."